

**LIBELED:** 2-3-54, N. Dist. Ga.; libel amended 3-16-54.

**CHARGE:** 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use; and 503 (b) (4)—the article was not a drug subject to 503 (b) (1), and prior to dispensing, its label bore the statement "Caution: Federal law prohibits dispensing without prescription."

**DISPOSITION:** Crews Drug Co., Inc., Atlanta, Ga., claimant, filed an answer denying that the article was misbranded as alleged and claiming that the article was exempt from the requirements of 502 (f) (1) under the provisions of 503 (b) (2) since it was to be dispensed only upon the prescription of a physician. Thereafter, on 3-16-54, the Government filed a motion to strike that portion of the claimant's answer claiming an exemption for the article, and in support of such motion, it claimed that the defense relied upon was insufficient in law. A motion was filed also to amend the libel to include the charge of misbranding within the meaning of 503 (b) (4). The motion to amend the libel was granted on 3-16-54.

The claimant filed a motion to amend its answer to include the claim that the article was also exempt from the labeling requirements of the Act by reason of the provisions of 503 (b) (1) (B). The motion was granted on 4-20-54. On 9-20-54, the Government's motion to strike was granted, there being no objection on the part of the claimant.

Subsequently, interrogatories were served upon the claimant by the Government and were answered. On 12-7-55, the court, upon motion of the Government and with the consent of the claimant, entered a decree condemning the article and ordering its destruction.

**4786. Apiol and ergotin compound.** (F. D. C. No. 38176. S. No. 21-585 M.)

**QUANTITY:** 17 pkgs., 24 24-capsule boxes each, at Philadelphia, Pa.

**SHIPPED:** 4-1-54, from Brooklyn, N. Y., by Jamco Co.

**LABEL IN PART:** (Box) "Penhurst Apiol and Ergotin Compound 24 \* \* \*  
Each capsule contains: Apiol 5 Min. Oil Pennyroyal 1/2 Min. Ergotin 4 Gr.  
Aloin 1/8 Gr. Vegetable Oil O. S. 10 Min."

**LIBELED:** 6-2-55, E. Dist. Pa.

**CHARGE:** 503 (b) (4)—the article was a drug subject to 503 (b) (1), and when shipped its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

**DISPOSITION:** 8-3-55. Default—destruction.

#### **DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\***

**4787. Quinine hydrochloride.** (F. D. C. No. 33786. S. No. 49-431 L.)

**INDICTMENT RETURNED:** 12-20-54, S. Dist. N. Y., against Sidney J. Cohen, New York, N. Y.

**ALLEGED VIOLATION:** The indictment alleged that, on or about 8-25-52, while a quantity of *quinine hydrochloride* was being held for sale, the defendant mutilated, destroyed, and removed a portion of the labeling displayed upon the drum containing the article, which acts resulted in the article being misbranded.

**CHARGE:** 502 (b) (1)—the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502 (e) (1)—the article failed to bear a label containing the common or usual name of the

\*See also No. 4785.

article; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use.

**DISPOSITION:** The defendant entered a plea of not guilty on 1-13-55, and the case came on for trial before a jury on 6-27-55. On 6-28-55, after presentation of the Government's evidence, the defendant changed his plea to guilty, and on 7-8-55, was sentenced to 8 months in prison and fined \$250.

**4788. Rutinfusion.** (F. D. C. No. 37900. S. No. 11-836 M.)

**QUANTITY:** 1 50-lb. drum at East Paterson, N. J., in possession of Merit Food Co., Inc.

**SHIPPED:** 1-1-55, from Station Yard, Wokingham, Berkshire, England, by Rutin Products, Ltd.

**ACCOMPANYING LABELING:** Leaflets designated "Rutinfusion makes 'Life as on a Summer's Day' " and "Rutinfusion (Technical Information)" and a number of printed package labels, the front panel bearing the statement "Merit rutinfusion \* \* \* Sole Distributor Merit Food Co., Inc. 890 River Drive East Paterson, N. J. Weight 2 Oz. Net" and the back panel bearing the statement "Rutin is described as being non-toxic \* \* \* Rutinfusion is specially grown and processed leaves and flowers of the buckwheat plant."

**RESULTS OF INVESTIGATION:** The package labels and leaflets were prepared locally for the consignee and were intended for use by the consignee as labeling for the article in 2-ounce packages for distribution for retail sale.

**LIBELED:** 3-23-55, Dist. N. J.

**CHARGE:** 502 (a)—the labeling of the article while held for sale contained false and misleading representations that the article was an adequate and effective treatment for overcoming capillary fragility; maintaining and restoring normal capillary strength; overcoming hypertension; preventing vascular accidents such as paralytic strokes; maintaining normal capillary strength for persons receiving medical treatment with thiocyanate drugs, salicylate drugs, and arsenical drugs; controlling pulmonary hemorrhage; overcoming internal bleeding; reducing the feeling of strain and fatigue after heavy or prolonged effort; strengthening the tiny blood vessels of the brain and body so that they may resist the effect of atomic fission; overcoming bodily failure after middle age; preventing premature decay; overcoming paralytic strokes caused by high blood pressure, eye conditions due to high blood pressure, and all forms of weakness of the circulatory system; preventing apoplexy and retinal hemorrhage; overcoming gastric hemorrhage and bleeding from the gums; preventing or delaying the advent of any ailments associated with age; strengthening and toning up the whole circulatory system, leaving the blood vessels vigorous and elastic; and for the treatment of asthma; and 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use for the purposes for which it was intended.

**DISPOSITION:** 4-27-55. Default—destruction.

**4789. Mineral oil.** (F. D. C. No. 37582. S. Nos. 7-803/4 M.)

**QUANTITY:** 2,300 gallons in 1 tank, at Oklahoma City, Okla., in possession of Roisman Products Co.

**SHIPPED:** 12-15-54, from Whiting, Ind.

**ACCOMPANYING LABELING:** Loose bottle labels bearing the following printed matter: "American Mineral Oil U. S. P. Heavy Contents 1 Pint Kent Directions Dose: One teaspoonful to one tablespoonful 2 or 3 times daily, or